UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 2 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF JAIME L. SEPULVEDA-TORO, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this memorandum and attached exhibits in opposition to Plaintiffs' motion to limit the opinions and testimony of Jaime L. Sepulveda-Toro, M.D.

Plaintiffs' motion to exclude certain expert testimony of Dr. Sepulveda distorts his opinions and disregards his distinguished qualifications and experience as well as his extensive review of the scientific literature. Dr. Sepulveda is an Obstetrician and Gynecologist focusing on treating female urinary incontinence and other pelvic floor disorders. (Plaintiffs' Motion, Ex. B, Expert Report on Gynemesh PS, Prolift, and Prosmia Devices at 1). He has practiced since 1992 and is board-certified in obstetrics and gynecology with a subspecialty certification in female pelvic medicine and reconstructive surgery. (*Id*.) During this time, Dr. Sepulveda has implanted thousands of slings, the vast majority of which used Prolene polypropylene. (*Id.* at 1-2). He has also conducted professional education activities for other doctors on polypropylene midurethral slings and over 500 physicians have watched him place a midurethral sling in his operating room. (*Id.* at 2).

As a result, Dr. Sepulveda has substantial experience with Defendants' medical devices, both as a surgeon counseling patients and as a teacher instructing other surgeons. Nonetheless, Plaintiffs seek to exclude him from offering certain opinions regarding Gynemesh PS, Prolift, Prosima, TVT, and TVT-O. Yet Dr. Sepulveda is well-qualified to offer these opinions on these devices and Plaintiffs' arguments to the contrary cannot withstand scrutiny:

- **Safety and Efficacy:** Plaintiffs' falsely argue that Dr. Sepulveda stopped using some of the devices because he believed they were unsafe, when, in truth, he testified that he only stopped because the devices had been decommercialized.

- **FDA Public Health Notices:** Plaintiffs ignore Dr. Sepulveda's service as an instructor and his membership in numerous professional societies in contending that he cannot testify as to whether surgeons can be expected to be aware of certain Public Health Notices. Moreover, they also fail to note his contemporaneous writing in 2008 regarding his teaching on complications while serving as an instructor.

- **Product Warnings and Brochures:** Dr. Sepulveda's extensive review of the scientific literature and experience as both a surgeon and instructor qualify him to testify to: (a) the risks and complications known by surgeons to be common with pelvic surgeries, and, (b) conversely, whether the complications and events unique to mesh are covered by the IFU.

- **Lack of Defect:** Plaintiffs mischaracterize Dr. Sepulveda's opinion that Defendants' devices are not defective as one requiring "design" expertise; regardless, he is qualified to offer this opinion based on his many years' service as a surgeon and instructor.

- **Explanted Materials and Pathological Opinions:** Plaintiffs' effort to exclude Dr. Sepulveda's opinion on the value of explanted materials and his critique of their experts' pathological opinions fails given his significant experience in cadaver labs.

- **Reliance on Studies:** Plaintiffs' scattershot arguments regarding Dr. Sepulveda's citation to and reliance on various studies misrepresents his testimony and the scientific literature.

- **Anatomical Considerations in Design:** Dr. Sepulveda's extensive experience in dissections and review of the literature qualifies him to testify on this subject.

- **Mechanical Cut Tape:** Plaintiffs' mischaracterize the literature and evidence in arguing Dr. Sepulveda may not testify as to the differences (or lack thereof) between mechanical-cut and laser-cut mesh.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

I. Plaintiffs' attempt to preclude Dr. Sepulveda from testifying that the subject devices are safe and effective rests on mischaracterizations of his opinions and testimony.

In his two separate reports, Dr. Sepulveda opines that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are safe and effective.[1] In support, he cites and discusses numerous studies, including (but not limited to):

- a study published in the Journal of Pelvic Medical Surgery in 2004 demonstrating the safety and efficacy of Gynemesh PS (Plaintiffs' Motion, Ex. B at 7);
- a multi-year study by a group of French surgeons on treat of prolapse that supported use of Gynemesh PS (*Id.*);
- numerous, separate randomized controlled trials demonstrating the anatomic superiority of Gynemesh PS and Prolift to native tissue, statistically significant subjective and quality of life improvements, and lower rates of reoperation (*Id.* at 8, n. 22);
- two separate studies on Prosmia showing its efficacy and positive safety profile (*Id.* at 14, n. 37);
- a 2004 study showing that use of TVT led to greater objective and subjective cure rates for urodynamic stress incontinence (Plaintiffs' Motion, Ex. C, Expert Report on TVT and TVT-O at 6, n. 10**)**;
- a five-year follow-up study showing that use of full length TVT surpassed the cure rates for previously used continence procedures (*Id.* at 10, n. 23); and
- several Cochrane Reviews and systemic reviews demonstrating that slings using TVT and TVT-O are as effective or more effective than Burch colposuspensions and pubovaginal slings while having less morbidity, shorter operating time, less hospital stay, less voiding dysfunction and lower complications (*Id.* at 12-13).

[1] He also has a third general report that addresses TVT, TVT-O, and, in particular, TVT Secur. Although this report contains similar opinions, Plaintiffs do not cite to it or appear to be challenging it.

And these are just the highlights. In all, Dr. Sepulveda devotes nearly 18 pages of his report on Gynemesh PS, Prolift, and Prosima and nearly 19 pages of his report on TVT and TVT-O to discussing the studies, reports, and other scientific literature supporting his opinion that these devices are safe and effective. (Plaintiffs' Motion, Ex. B at 3-20; Plaintiffs' Motion at 3-21).

Plaintiffs stand no chance of attacking these authorities, Dr. Sepulveda's substantial experience and credentials, or his methodology in relying on both his experience and review of the scientific literature to opine that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are safe and effective. So, they instead resort to distorting his deposition testimony. These mischaracterizations do not hold up and cannot support any exclusion of his opinions.

First, Plaintiffs falsely contend that Dr. Sepulveda agrees with the FDA's classification of Gynemesh PS, Prolift, and Prosima as high risk devices. (Plaintiffs' Brief at 6). In the portion of his testimony quoted by Plaintiffs, Dr. Sepulveda merely states the he will instead "agree with the approval that the FDA has" of those devices and that he is "not going to challenge the FDA" on its classification. (*Id.* at 5). Dr. Sepulveda does not claim any regulatory expertise and his testimony here makes it quite clear that rather than agree with the FDA's rating, he simply and quite sensibly does not intend to opine on the FDA's regulatory process. This was further clarified later in his deposition when he refused Plaintiffs' attempts to label the devices high risk or low risk. (Sepulveda March 30, 2016 Dep. (attached as Ex. A) 250:2 – 251:3 (testifying that "I will not go with low risk or high risk" and that "I think that whole terminology is so – is so nonspecific.")). As a result, Dr. Sepulveda's deposition testimony is not in any way inconsistent with his opinion that Gynemesh PS, Prolift, and Prosima are safe and effective.

Second, Plaintiffs' suggestion that Dr. Sepulveda stopped using Gynemesh PS, Prolift, and Prosima for safety reasons is far from the truth. Instead, Dr. Sepulveda testified at his

deposition that fear of lawsuits (rather than harm to patients) caused him and other clinicians to question continued use of the devices:

> Q: At any point after the July, 2011, FDA warning, did you decide to stop using Prosima, Prolift or Gynemesh transvaginally?
>
> A: I think that everyone look[ed] at it and everyone stop[ped] using it for the wrong reasons, less because of evidence, and more because of the -- of the fear of being involved in litigation, which is real, and being involved in a situation having to explain themselves when there is not a clear -- a clear picture about the reality of it.

(*Id.* at 248:6 – 15).

Dr. Sepulveda therefore stopped using the devices only after he had no other choice. This testimony does not run counter to his opinion as to the device's safety and efficacy.

Third, Plaintiffs' attack on Dr. Sepulveda for his failure to remember at his deposition the names of certain, multi-year studies on TVT and TVT-O is particularly disingenuous. At his deposition, Plaintiffs' counsel was quick to say that "this is not a memory test" when he asked Dr. Sepulveda to identify studies measuring periods of five years or more:

> Q: That's fine, and ***this is not a memory test***, and I'm sure your lawyer will be happy to walk you through when we get to the courthouse, but just sitting here right now, you can't name me one study that meets the parameters I just defined, correct?
>
> A: Yes, I just, I just mentioned them to you.
>
> Q: Which, TOMUS?
>
> A: Tommaselli.

(Sepulveda April 8, 2016 Dep. (attached as Ex. B) at 96:16-24 (emphasis added)).

Plaintiffs' change of tune and attempted "gotcha" is wrong. Plaintiffs' counsel was right that depositions are a not a memory test. Instead, what matters are the sources Dr. Sepulveda has actually relied on in reaching his opinion. And, on that score, Plaintiffs conveniently fail to

mention that Dr. Sepulveda cites to seven separate long-term studies of five years or more on just one page of his TVT and TVT-O report alone. (Plaintiffs' Motion, Ex. C at 11).

Finally, Plaintiffs' suggestion that Dr. Sepulveda has somehow admitted that these studies are "outliers" is wrong on its face. (Plaintiffs' Brief at 5). Nothing in the portion of his testimony quoted by Plaintiffs indicates any agreement by him with Plaintiffs' arguments or suggestions. (Plaintiffs' Brief at 5-6). Dr. Sepulveda therefore has provided more than sufficient support for his opinion that TVT and TVT-O are safe and effective and Plaintiffs' request to exclude this opinion should be denied.

II. Dr. Sepulveda may testify regarding the FDA's 2008 Public Health notice.

Dr. Sepulveda's opinion that fellow pelvic floor surgeons would know of the FDA's 2008 Public Health Notice on surgical pelvic mesh is not, as Plaintiffs claim, "pure conjecture." (Plaintiffs' Brief at 7). In arguing otherwise, Plaintiffs ignore Dr. Sepulveda's experience as an instructor, memberships in multiple professional societies, and numerous other interactions with fellow clinicians.

Dr. Sepulveda has taught surgeons on polypropylene midurethral slings for numerous years and over 500 physicians have watched him place a midurethral sling in his operating room. (Plaintiffs' Motion, Ex. B at 1-2). He is a member of the American Urogynecologic Society, American Urogynecologic Association, International Urogynecology Association, and the International Continence Society and a fellow of the American College of Obstetrics and Gynecology and the American College of Surgeons. (*Id.*). Indeed, as he states in his report, all of "[t]he professional education activities provided the opportunity to exchange knowledge among surgeons." (*Id.* at 18).

As a result, Dr. Sepulveda has interacted for multiple years on a near constant basis with fellow practitioners as both a surgeon and instructor regarding the devices at issue. These experiences uniquely qualify him to say whether it likely that fellow surgeons would be aware of the 2008 Public Health Notice. *See Kumho Tire Co., Ltd. V. Carmichael*, 526 U.S. 137, 156 (1999) (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

It is also interesting to note that Plaintiffs fail to address his contemporaneous writing on this subject in 2008 at the time of the Public Health Notice, which was produced in this litigation. (*See* 10/22/08 Email (ETH.MESH.07383398-401) (attached as Ex. C)). This writing was also reproduced in its entirety within pages 31-37 of his TVT Secur General Report, which pertains to his IFU opinions, complications, and his activities as an instructor. Upon viewing this documentation, it is clear that Plaintiffs' attempt to preclude Dr. Sepulveda from offering such testimony is disingenuous and should therefore be rejected.

III. Dr. Sepulveda may testify to the adverse event risks known by pelvic floor surgeons and that Ethicon's warnings cover the adverse events said to be unique to mesh.

The job of an expert witness is to provide the facts to which the court can apply the law. So long as the expert has supplied the facts in a form consistent with the law, she has done her job. It is not the expert's job to provide the Court with the law. In fact, this Court has in the past excluded testimony which not only stated facts but also expressed a legal conclusion. *See In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872 (S.D. W. Va. 2014) at *20, *citing United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). And similarly the Court should exclude warnings testimony which fails to follow the appropriate legal standard. (*See* Defendants Johnson & Johnson and Ethicon Inc.'s Memorandum in Support of Motion to Exclude Peggy Pence, Ph.D., [Doc. 2078], filed April 21, 2016 at pp. 6-7 (collecting

authority)). So, the important question here is whether Dr. Sepulveda's testimony was consistent with the law to be applied to the case, not whether he could articulate the governing legal standard.

The legal standard. Dr. Sepulveda's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling: "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbot*

Laboratories, Inc., 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd*., 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The IFUs for Gynemesh PS, Prolift, and Prosima state that "[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing" the devices. (Plaintiffs' Motion, Ex. B at 16). The TVT IFU says "[u]sers should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system" and that it "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)." (ETH.MESH.00875456 (attached as Ex. D)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH. 02340829 (attached as Ex. E)).

So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" are "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery at the time the device was implanted. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the very least, unique to the use of mesh.

Dr. Sepulveda's qualifications. Dr. Sepulveda is well-qualified to render such an opinion. He has over 20 years of practice in the field and has performed over 2,000 synthetic midurethral slings since 1998. (Plaintiffs' Motion, Ex. B at 1-2). Moreover, unlike some of the

experts Plaintiffs offer regarding the adequacy of Defendants' warnings, Dr. Sepulveda has actually used the devices, IFUs, and brochures at issue in his practice.[2] (*Id.* at 2).

In addition, as an instructor for Ethicon, he has conducted surgical anatomy laboratories with the use of models and cadevers, consensus conferences among experienced users, surgical demonstrations in the operating room, and didactic lectures. (*Id.* at 18; Plaintiffs' Motion, Ex. C at 22; 10/22/08 Email). In this professional education role, Dr. Sepulveda covered and taught to fellow surgeons the IFUs at issue. (Ex. A, 275:24 – 275:16). As he testified at his deposition, the IFU was taught at "every single lab" and that "as a preceptor or as teacher, you need to know that IFU by – by steps and know not only what it says, but what really says in terms of mechanics." (*Id.*). Dr. Sepulveda further noted in his reports that "[a]ll these activities offer the opportunity to address the complications and details of the surgery along with the interpretation of the IFU." (Plaintiffs' Motion, Ex. B at 18; Plaintiffs' Motion, Ex. C at 22).

His opinion also rests literature and professional association statements. Yet Dr. Sepulveda's opinion is not based solely on his lengthy and distinguished clinical experience. Instead, Dr. Sepulveda also relies on an in-depth review of the medical literature, as outlined in his reports. These include numerous studies comparing mesh to non-mesh surgery.[3] He has also

[2] Plaintiffs incorrectly suggest that Dr. Sepulveda is not familiar with the IFU for TVT because he testified that the last time he reviewed it was six years ago. (Plaintiffs' Brief at 8). Plaintiffs fail to note that Dr. Sepulveda also testified that he is aware of the contents of the IFUs and his substantial experience with the IFUs, as detailed above, proves the point. (Ex. A at 122:8-22).

[3] These include: Carey M, Higgs P, Goh J, Lim J, Leong A, Krause H, Cornish A. *Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial*, BJOG. 2009 Sep.116(10):1380-6; Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. *Trocarguided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial*, Obstet Gynecol. 2011 Feb;117(2 Pt 1):242-50; Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; Nordic Transvaginal Mesh Group, *Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse*, N Engl J Med. 2011 May 12;364(19):1826-36. doi: 10.1056/NEJMoa1009521. Erratum in: N Engl J Med. 2013 Jan 24; 368(4):394; Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER, *One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse*, Am J Obstet Gynecol. 2012 Jan;206(1):86.e1-9; Halaska M, Maxova K, Sottner O, Svabik K, Mlcoch M, Kolarik D, Mala I, Krofta L, Halaska MJ, *A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse*, Am J Obstet Gynecol. 2012 Oct;207(4):301.e1-7; El-Nazer MA, Gomaa IA, Ismail Madkour

reviewed and relies on literature on dyspareunia and other complications common to pelvic floor surgeries.[4] Conversely, Dr. Sepulveda has also reviewed literature on complications unique to mesh surgery, such as mesh exposure.[5] Further, he has reviewed and relies upon literature on TVT and TVT-O, including long term studies on the devices' efficacy and complications.[6]

In his opinion, complications of traditional non-mesh surgery include voiding dysfunction, permanent retention of urine, catherization, de novo urge incontinence, urinary tract infections, hernias, hematomas, fascial sling exposure, and granulomas. (Plaintiffs' Motion, Ex. B at 4-12; Plaintiffs' Motion, Ex. C at 5-7). The use of native tissue surgical repair for prolapse has been associated with high rates of recurrence of 30% to 50%. (Plaintiffs' Motion, Ex. B at 5). The Burch procedure has been shown to increase the risk of vaginal prolapse and also cause pain, sexual dysfunction and dyspareunia. (Plaintiffs' Motion, Ex. C at 5-6).

With mesh surgery, there are fewer wound complications than with non-mesh surgery and there are usually mesh exposures which can be conservatively managed on an outpatient

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WA, Swidan KH, El-Etriby MA, *Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study*, Arch Gynecol Obstet. 2012 Oct;286(4):965-72; Qatawneh A, Al-Kazaleh F, Saleh S, Thekrallah F, Bata M, Sumreen I, Al-Mustafa M, *Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study*, Gynecol Surg 2013; 10:79–85; Svabik K, Martan A, Masata J, El-Haddad R, Hubka P., *Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial*, Ultrasound Obstet Gynecol. 2014 Apr;43(4):365-71; Dos Reis Brandão da Silveira S, Haddad JM, de Jármy-Di Bella ZI, Nastri F, Kawabata MG, da Silva Carramão S, Rodrigues CA, Baracat EC, Auge AP, *Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment*, Int Urogynecol J.2015 Mar;26(3):335-42. (*See* Plaintiffs' Motion, Ex. B at 8, n. 22 (citing all of the studies listed above)).

[4]These include: Francis WJ, Jeffcoate TN, *Dyspareunia following vaginal operations*, J Obstet Gynaecol Br Commonw. 1961 Feb;68:1-10; Lowman JK, Jones LA, Woodman PJ, Hale DS, *Does the Prolift system cause dyspareunia?*, Am J Obstet Gynecol. 2008 Dec;199(6):707.e1-6. (*See* Plaintiffs' Motion, Ex. B at 12, ns. 25 and 26 (citing and discussing these studies)).

[5] These include: Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V; Pelvic Surgeons Network, *Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse,"* Int Urogynecol J. 2012 Jan;23(1):5-9; Benbouzid S, Cornu JN, Benchikh A, Chanu T, Haab F, Delmas V, *Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up*, Int J Urol. 2012 Nov;19(11):1010-6. (*See* Plaintiffs' Motion, Ex. B at 12-13 ns. 31 and 33 (citing and discussing these studies)).

[6] (*See* Plaintiffs' Motion, Ex. C at 11 ns. 27 (citing numerous, long-term studies on TVT and TVT-O)).

basis. Studies show that anatomic superiority of Gynemesh PS and Prolift and improvements in bowel, prolapse, sexual function, urinary incontinence or urgency, voiding difficulty, and vaginal pressure/bulge. (Plaintiffs' Motion, Ex. B at 9). In addition "[t]he most recent Cochrane Review demonstrates that there are lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination with permanent polypropylene mesh like Gynemesh PS compared to native tissue repair and there is no difference in repeat surgery for incontinence or dyspareunia versus native tissue repair." (*Id.* at 10). Studies of Prosima have produced similar results. (*Id.* at 15). Also, studies and "[s]urgical experience made clear that patients treated with TVT had less voiding dysfunction, less wound complications and less retention than the historic numbers from patients treated with pubovaginal slings, needle procedures or open retropubic procedures." (Plaintiffs' Motion, Ex. C at 13-14).

"Mesh exposure is the only unique complication with Gynemesh PS and and Prolift," but, "[i]n many cases it can be treated conservatively with estrogen or a simple office procedure to excise the exposure." (Plaintiffs' Motion, Ex. B at 12). Also studies have demonstrated a low mesh exposure rate for patients, including a study with a 54 month follow-up that reported an 85% cure rate, no reoperations for recurrence, a 5.3% mesh exposure rate (of which two cases were excised and two resolved with estrogen), and no infections. (*Id.* at 13). The complications unique to synthetic slings are erosions and extrusions. (Plaintiffs' Motion, Ex. C at 17-20). Yet studies have shown low complication rates, and, in at least one study, none of the patients having any sign of tissue reaction, erosion, or tape protrusion at their 5-year follow-up. (*Id.* at 20).

The risks of dyspareunia and hematomas are well known to surgeons performing stress incontinence repairs and are not limited to mesh surgeries. (Plaintiffs' Motion, Ex. B at 11-13). Other complications with mesh slings are of the same type as those with non-mesh surgery. (*Id.*

at 8-14). Studies have shown a cure rate for mesh surgeries in the range of 85% or higher, with a much lower cure rate shown for non-mesh surgeries. (Plaintiffs' Motion, Ex. B at 8-9, 13; Plaintiffs' Motion, Ex. C at 20).

Dr. Sepulveda's Opinions. Based on these facts, it is Dr. Sepulveda's opinion that the IFUs for Gynemesh PS, Prolift and Prosmia, which specifically identify, among other things, those unique risks, give adequate information to the surgeons who are the intended users:

> I have reviewed these IFUs and find them adequate and complete for its use in the operating room by the intended users. As a surgeon, I understand that the IFU is not a comprehensive guide for the surgical treatment of POP. The IFU builds on the knowledge that we as pelvic floor surgeons have acquired through prior education, instruction and experience and warns that users should be pelvic floor surgeons familiar with surgical procedures and techniques regarding pelvic floor repair and nonabsorbable meshes before using the device. Moreover, the IFUs on the very first page state that training is recommended and available. The IFU adequately informs surgeons of the use of Gynemesh PS, Prolift, Prosima and the potential risks and complications.

(*Id.* at 39). Regarding the brochures for these devices, he opines that:

> I have used the Prolift and Prosima patient brochures in my practice. Both allow a patient to construct a base to be used in the conversation about the procedure. These brochures are not meant to supplant the informed consent process, but rather are a resource for additional information and mention complications inherent to continence procedures. The IFU, surgical technique guide, surgeons resource monograph, patient brochure, professional education, medical literature, the 2008 and 2011 FDA Public Health Notifications discuss potential complications to be addressed in the informed consent process and were available to surgeons.

(*Id.* at 18).

Based again on his review of the scientific literature and his clinical experience, Dr. Sepulveda similarly opines that the IFUs for TVT and TVT-O, which also specifically identify, among other things, unique risks such as erosion and extrusion, give adequate information to the surgeons who are the intended users:

> I have reviewed the TVT and TVTO IFUs and find them adequate and complete for its use in the operating room by the intended users. As a surgeon, I understand that

> the IFU is not a comprehensive guide for the surgical treatment of SUI. The IFU builds on the knowledge that we as pelvic floor surgeons have acquired through prior education, instruction and experience. The IFU adequately informs surgeons of the use of the TVT and TVTO and the potential risks and complications.

(Plaintiffs' Motion, Ex. C at 22). With respect to these devices' brochures, he states that:

> I use the TVT and TVTO patient brochures in my practice. Both allow a patient to construct a base to be used in the conversation about the procedure. These brochures are not meant to supplant the informed consent process, but rather are a resource for additional information and mention complications inherent to continence procedures. The IFU, patient brochure, professional education, medical literature, and the 2008 FDA Public Health Notification discuss potential complications to be addressed in the informed consent process for a MUS and were available to surgeons.

(*Id.* at 22-23).

This is testimony that directly addresses the appropriate legal standard, which cannot be applied without evidence of what is "commonly known" to the class of foreseeable users about the risks of the surgery. Because it is consistent with the applicable legal test, it "fits" this case whether or not Dr. Sepulveda himself can testify to the details of that law.

IV. Dr. Sepulveda may testify that the devices are not defective.

Plaintiffs' contention that Dr. Sepulveda is unqualified to say that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are not defective rests on their erroneous characterization of this as a "design" opinion. (Plaintiffs' Brief at 8-9). This is a ruse. Dr. Sepulveda's opinion instead pertains to the design of the device as to its functionality when implanted by the pelvic surgeon, its biocompatibility, utility, desirability and safety and efficacy as assessed by the medical literature and as compared to alternative surgical procedures. For this he is certainly qualified.[7]

[7] Indeed, this Court's rulings show that even if this testimony was a design opinion, Dr. Sepulveda need not be a biomedical engineer to offer it. *See Trevino v. Boston Scientific Corporation*, No. 2:13-CV-01617, 2016 WL 2939521, at *4-5 (S.D. W. Va. May 19, 2016) (rejecting argument that a practicing urologist was not qualified to opine on biomaterials or on mesh design as he had "years of experience treating pelvic floor disorders, as well as complications resulting from the implantation of transvaginal mesh" and his "experience removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case.") ; *Tyree v. Boston Science Corporation*, 54 F. Supp. 3d 501, 549-550 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) (holding

Dr. Sepulveda possesses substantial experience as a surgeon and educator. As detailed above, he has used these devices thousands of times and therefore has the specialized knowledge sufficient to opine on how the devices should be tensioned and placed and how their design suits surgical needs. Moreover, Dr. Sepulveda has studied biomedical engineering in his private practice and spoken repeatedly with biomedical engineers. (Ex. A, 98:10-99:2 (testifying that "I have devoted years to understand [biomedical engineering], to read about it beyond what any other physician that I ever met have done" and that "I have studied, I have spoken to biomedical engineers, but specifically it's a passion and dedication that I have to understand it")). He has also given input to engineers on the design of fibers used in Ethicon's mesh devices as well as input on the design of other medical devices used in surgery. (*Id.* 99:15-21 (design input for surgical staplers, retractors, and circumferential needles), and 102:11-19 (input on fibers used by Ethicon)). Plaintiffs' arguments should therefore be rejected.

V. Dr. Sepulveda may testify as to the value (or lack thereof) in explants and offer critiques of Plaintiffs' experts pathological opinions.

Plaintiffs wrongly seek to exclude certain testimony by Dr. Sepulveda because he is not pathologist. Plaintiffs' arguments are baseless. Although Dr. Sepulveda is not a pathologist, he has wealth of relevant experience that qualifies him to offer the opinions at issue. Dr. Sepulveda has taught extensively in Ethicon's cadaver labs, performing dissections one or more times a month (Sepulveda Trial Testimony, September 30, 2015 (attached as Ex. F) at 79:25 – 82:18).[8] He has also written a manual on dissections and how to make the best of specimens. (Ex. A at 17:5-13). He has performed dissections not only for fellow surgeons, but also for Ethicon's

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that an obstetrician and gynecologist who had no experience in designing mesh products was qualified to testify as to the design of slings as "[h]e has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products").

[8] Dr. Sepulveda's trial testimony is taken from a Texas State Court action, *Caveness v. Kowalcyzk, et al*, No. DC-14-04220, in which Ethicon retained Dr. Sepulveda in response to similar claims asserted by Plaintiffs' here.

biomechanical engineers and sales representatives. (Ex. F at 83:20 – 84:14). As Dr. Sepulveda details in his report, he has "devoted over a decade to study the anatomy of the obturator an area in which I done surgery and have explored with the systematic study of its anatomy using imaging and cadaver dissection" and that he has "studied the anatomy of this space through the dissection of over 300 cadaver specimens and through MRI imaging of cadaver and patients." (Plaintiffs' Motion, Exs. B at 2 and C at 2).

Thus, Dr. Sepulveda has more than sufficient expertise. As a surgeon and instructor in cadaver labs, Dr. Sepulveda can opine as to the forces the devices are subject to in surgery compared to dissections. Moreover, these same experiences qualify Dr. Sepulveda to offer the critiques of Plaintiffs' experts set forth in his report regardless of the label (whether pathological or not) Plaintiffs seek to place on them. As noted in his report, his background in basic sciences, specifically his formal training in molecular pharmacology including bench work preparation of cytotoxicity assays, gives him unique expertise in implants science. (Plaintiffs' Motion, Ex. B at. 3). Plaintiffs' effort to exclude these opinions should therefore be rejected.

VI. Dr. Sepulveda may testify as to the general number of studies done on the devices and offer opinions on degradation.

Plaintiffs' overwrought characterization of Dr. Sepulveda's reference to the general number of studies performed on the devices at issue as "outlandish" and "conjecture" do not support any limits on his testimony. (Plaintiffs' Brief at 10-11). As detailed above, Dr. Sepulveda cites to and discusses for pages of his reports numerous studies of Gynemesh PS, Prolift, Prosima, TVT, and TVT-O. *See supra.* His list of resources relied upon contains even more. (List of Materials Relied Upon For Gynemesh PS, Prolift, Prosima, TVT, and TVO-O Reports (attached as Ex. G)). Dr. Sepulveda has performed an exhaustive review of the relevant scientific literature and not just for his work in this case, but also in his daily practice.

(Plaintiffs' Motion, Exs. A at 3 (noting his regular reading of mesh research) and B at 2 (noting his regular reading of sling research)). He is more than qualified and able to offer opinions as to the general numbers of studies performed on the devices.

Plaintiffs attempt to exclude Dr. Sepulveda's opinions regarding degradation of the devices is equally without merit. In the portion of the testimony cited by Plaintiffs, Dr. Sepulveda does not disclaim sufficient expertise to testify regarding degradation of polypropylene. Rather, his testimony is entirely consistent with his reliance on studies (or the lack thereof) performed by others regarding degradation. As Dr. Sepulveda made clear in an earlier deposition, he has reviewed the scientific literature and not found any that support a theory of degradation. (Ex. A at 176:5 – 177:14 (testifying that "there's no evidence" of degradation and that "degradation has not been defined in a reproducible scientific way to have – to be present, or if present, to have any consequences in clinical outcomes") and 282:14 – 284:21 (testifying that he had reviewed the various studies referenced by Plaintiffs' counsel and others and that "I have not seen one yet that proves degradation with any definition that I've given of degradation")). He has also reviewed the data cited by Plaintiffs' experts and finds them without merit:

> These case reports and case series of explants lack reliability and one cannot drawn any causal inference from them or extrapolate their reported SEM findings to the larger population. In the referenced Clave study there were several methodologic flaws. Moreover, only a minority of the explants were reported to have surface cracking and degradation and oxidation were not shown on chemical analyses. While the purported surface changes were hypothesized to lead to adverse clinical outcomes, these hypotheses have not been confirmed.

(Plaintiffs' Motion, Ex. B at 20)

Moreover, the Court has previously found that a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him to opine on "how the

product reacts inside the body."[9] Like the physicians in those cases, Dr. Sepulveda is a skilled urogynecologist with 24 years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. *See supra*. He has performed thousands of stress incontinence surgeries, and has placed the vast majority of the slings through the transobturator route. His opinions are premised upon clinical observations from performing thousands of procedures involving mesh. (Plaintiffs' Motion, Ex. A at 1-2). Accordingly, Dr. Sepulveda is well-qualified to offer opinions regarding degradation.

VII. Dr. Sepulveda may testify that the design of TVT-O takes into account anatomical considerations.

Plaintiffs incorrectly argue that Dr. Sepulveda needed to have been involved in the design process in order to opine that the TVT-O's design accounts for anatomical considerations, in particular the hammock of the suburethra and the periurethral tissue. As detailed above, Dr. Sepulveda has performed numerous dissections and even written a manual instructing others on how to perform dissections and make use of specimens. When instructing in Ethicon's cadaver labs, Dr. Sepulveda necessarily broke-down for fellow surgeons the anatomical effects of mesh devices. Indeed, he notes in his TVT and TVT-O report that he has "dissected the [urethral] area in cadavers extensively and been able to confirm the support to the urethra in this area." (Plaintiffs' Motion, Ex. C at 8; *see also* 8 n. 15-17 (anatomical studies), 20 (anatomic considerations of the TVT-Os design) and 20 n. 66 (*citing* relevant literature)). Accordingly, Dr. Sepulveda need not have been present at the design of TVT-O to opine as to whether it is consistent with the anatomical considerations he has witnesses first hand in countless dissections. Plaintiffs' request to exclude such testimony should be denied.

[9] *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *26 (S.D. W. Va. Apr. 24, 2015); *see also Trevino*, No. 2:13-CV-01617, 2016 WL 1718836 at *4-5 (rejecting challenge to practicing urologist whose "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction").

VIII. Dr. Sepulveda may testify that mechanical cut tape is not defective.

Plaintiffs misconstrue the scientific literature and evidence in trying to exclude Dr. Sepulveda's testimony that mechanical cut tape is not defective. Dr. Sepulveda cites and discusses in several pages of his TVT and TVT-O report the studies and literature supporting his opinion. This includes studies and documents supporting his opinion that mechanical cut tape is not defective.[10] Moreover, it is irrelevant that Dr. Sepulveda identified just one randomized controlled study of Ethicon's TVT-O at his deposition given that they are not a memory test.

Plaintiffs' insistence that the lack of any clinical studies comparing the differences between mechanical cut tape and laser cut tape makes Dr. Sepulveda's opinions unreliable is nonsensical. Plaintiffs do not (and cannot) cite any authority suggesting that such a study must have been performed in order for Dr. Sepulveda to offer his opinion. Nonetheless, Dr. Sepulveda has extensively reviewed the medical literature and seen where Ethicon concluded that there was no difference between mechanical cut tape and laser cut tape. He has seen no difference in his clinical practice.

Finally, Dr. Sepulveda cannot be faulted for supposedly failing to consider "other forms of data," as Plaintiffs argue. Tellingly, Plaintiffs can point to only one other piece of "data"—an internal Ethicon PowerPoint presentation. Setting aside that this presentation cherry-picked from millions of company documents is not "data," Dr. Sepulveda's opinion cannot be excluded merely because he may not have reviewed a single document of Plaintiffs' choosing. This is particularly so given his lengthy citation and discussion of the data supporting his conclusion.

[10] (*See* Plaintiffs' Motion, Ex. C at 24 ("Review of internal documents from Ethicon regarding the medical interpretation of biomechanical engineering test data shows no difference on the product physical characteristics. . . . Both mechanical cut mesh and laser cut mesh in the TVT and TVTO behave the same in vivo and the data show no significant difference in efficacy or complication rates in studies that were performed before and after 2007 when laser cut mesh was utilized. . . . This evaluation is in agreement with my clinical observations in the operating room using mechanical cut mesh and laser cut mesh."); *id.* at 23 ("There was no data (and still is none) indicating that modification from mechanical to laser cutting would result in any potential effects on clinical outcomes…")).

Moreover, Plaintiffs' complaint that his review is selective is rich as they fail to mention that there are other internal Ethicon documents (which Dr. Sepulveda reviewed) showing no differences whatsoever between mechanical cut tape and laser cut tape. (*See* ETH.MESH.01784825 (attached as Ex. H) (study cited stating that "[t]he ridigity of the Mechanically cut and Laser cut for the samples in the cross direction was similar[.] This should result in no clinical differences in this respect.")). So, Plaintiffs' arguments should be rejected.[11]

CONCLUSION

Dr. Sepulveda's distinguished and lengthy career, together with his extensive review of the scientific literature and many interactions with fellow colleagues, qualifies him to offer the opinions at issue. His methodology of relying on these experiences and interactions and his review of the literature in reaching his conclusion is sound. The Court should enter an order denying Plaintiffs' motion to limit the opinions and testimony of Dr. Sepulveda.

[11] Also, Plaintiffs' request to exclude use of the term "gold standard" is, at best, moot. Dr. Sepulveda testified that he prefers "clinical standard" rather than "gold standard," which he views as a marketing term. (Ex. A at 74:15 – 75:6). Finally, Plaintiffs misread Dr. Sepulveda's report in claiming he opines that the Section 510(k) process demonstrated TVT's tolerability and safety. He instead cites to a 2001 study by Folconer, Soderberg, Blomgren, and Ulmsten in support of his opinion that "tolerability and safety has been proven by the predicate device and graft, in this case the TVT Prolene polypropylene mesh tape." (Plaintiffs' Motion, Ex. C at 24 n. 72). Dr. Sepulveda does not intend to opine on the Section 510(k) process in a manner inconsistent with this Court's prior rulings

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on August 8, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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